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INTUITIVE.

November 26, 2019

Dr. Eric Pifer, Chief Medical Officer
Lee Domanico, Chief Executive Officer
Jon Friedenberg, President & Chief Operations Officer
Marin General Hospital
250 Bon Air Road
Greenbrae, California 94904

Dear Mr. Pifer, Mr. Domanico, and Mr. Friedenberg:

We understand that Marin General Hospital is using or considering using "refurbished" EndoWrist® instruments, obtained from and/or modified by a third party for use beyond the programmed number of uses. The programmed number of uses, as indicated in the product labeling, represents the validated intended use of the product documented and submitted to authorities. Intuitive strongly discourages the procuring of its products through unauthorized channels and/or using its products that have been modified to work beyond the pre-programmed number of uses.

Extended Instrument Use Can Impact Product Performance and Patient Safety

All Intuitive products are designed and tested to achieve a targeted level of safety, precision, and dexterity over the programmed number of instrument uses. Gradual degradation of the instrument occurs both from use in surgery as well as repeated cleaning and sterilization cycles required between uses. Examples of degraded performance may include, but are not limited to:

- Unintuitive motion (i.e. instruments do not track well with master manipulators; unexpected motion or stalls);
- Insufficient grip force;
- Dull or damaged scissor blades;
- Worn/damaged cables.

With continued use beyond the instrument's determined useful life, the wear and tear from these additional uses may reduce these levels of safety, precision and dexterity.

In addition, in light of the prescribed cleaning and sterilization processes for the Intuitive instruments, device handling and modification by an outside party that deviates from validated processes submitted and cleared by regulatory authorities may cause instrument damage that could create patient safety issue. Third party remanufacturers or refurbishers may use non validated or incompatible cleaning agents and/or disinfection/sterilization processes, which are likely to damage the instruments, negatively affecting product performance.

Further, third party remanufacturers or refurbishers may damage the instrument's internal mechanisms that interface with the robotic system and allow Intuitive to monitor the device. In sum, the use of third party remanufacturers or refurbishers may affect the operation of the Instrument thereby jeopardizing patient safety.

Extended Instrument Uses: Impact to Regulatory Clearances and Safety Precautions

All of Intuitive's medical devices, including EndoWrist®instruments, are evaluated by the United States Food and Drug Administration ("FDA") and/or other international regulatory agencies to assess the safety and effectiveness of a device over its intended life and are cleared for use by those regulatory authorities.

Refurbishing activities performed by an unauthorized third party violate the U.S. Federal Food, Drug, and Cosmetic Act ("FDC Act") and the regulations promulgated and enforced thereunder by the FDA when

PLAINTIFFS EXHIBIT 293

such activities do not bring products to established specifications or when such activities change intended uses. Deviation from these specifications might prevent such products from performing properly, thereby subjecting patients to significant risk. By using a third party remanufacturer or refurbisher, the hospital has no way to know whether the refurbished instrument meets the rigorous specifications as established by Intuitive Surgical and cleared by the FDA or other regulators. Moreover, the regulatory clearance provided to Intuitive by the FDA and other regulatory authorities may not apply to products that have been remanufactured or refurbished by unauthorized third parties.

Refurbishing activities performed by an unauthorized third party that change intended uses or modify the control mechanisms of the device may constitute the entry of adulterated and misbranded products to the marketplace. Specifically, the manufacture and entry into commerce of a medical device that does not meet specifications renders the product adulterated under 21 U.S.C. § 351. Moreover, any modification to allow for use of a da Vinci product beyond its labeled useful life exceeds the scope of the original clearance by expanding the FDA cleared indications for use. Engaging in such activities without first obtaining a new clearance to do so misbrands the product under 21 U.S.C. § 351. The citied provisions of the FDC Act and FDA's implementing regulations help to protect the public health by ensuring that medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed and that the products were designed, manufactured and serviced in a controlled manner to ensure that they meet designated specifications.

Furthermore, acquiring da Vinci System surgical products through unauthorized channels may violate the hospital's internal policies, which violation may include not obtaining proper patient's and/or surgeon's consent for the use of an altered or adulterated device on the patient.

Your Contract with Intuitive

We presume that you are aware that, in connection with Marin General Hospital's purchase of *da Vinci* Surgical products, Marin General Hospital entered into Sales, License, and Service Agreements in 2007 and 2013 (each referred to herein as "Agreement" or collectively as "Agreements").[1] Using instruments beyond the programmed number of uses is a material breach of the Agreements. Here are summarized terms of the Agreements that you might wish to consider:

- Instruments and Accessories are subject to a limited license to use those Instruments and Accessories with, and prepare those Instruments and Accessories for use with, the System. Any other use is prohibited, whether before or after the Instrument or Accessory's license expiration, including repair, refurbishment, or reconditioning not approved by Intuitive. This license expires once an Instrument or Accessory is used up to its maximum number of uses specified in the documentation accompanying the Instrument or Accessory. [2007 Agreement § 2.5(b), 2013 Agreement § 8];

- Under the section titled "Use of System", Customer agreed that it will not, nor will Customer permit any third party to, modify, disassemble, reverse engineer, alter, or misuse the System or Instruments and Accessories. Further, if Customer fails to comply with the requirements of this section, any warranties applicable to the System will become void and Intuitive may terminate the Agreement for material breach. [2007 Agreement § 2.3(a) and § 5 , 2013 Agreement § 3.4];

- Moreover, Intuitive will not be liable for, and Customer will indemnify and hold Intuitive harmless from and against, any claims or damages caused by Customer's failure to comply with the requirements of the section titled "Use of System". [2007 Agreement § 2.3(a) and § 6.2, 2013 Agreement § 11.2].

1 Capitalized terms in this section have the same meaning as set forth in the Agreement.

In addition to the above, Intuitive believes that it has important intellectual property rights in the da Vinci system and its instruments. You may want to be sure that a vendor offering "reprogrammed instruments" is not violating intellectual property rights that belong to Intuitive.

Based on the terms of the Agreement and the patient safety implications of the Systems being used with instruments refurbished by an unauthorized third party, Intuitive may no longer accept your service calls for such Systems. Should Intuitive or its personnel determine, after having accepted a service call or a purchase order for a service call, such as after an Intuitive Field Service Engineer arrives at your site for a service call, that the System has been used with instruments refurbished or modified by an unauthorized third party, Intuitive may not provide service for such a System. Please contact Intuitive's Director of External Affairs, Dan Jones (dan.jones@intusurg.com), if you have any further questions.

Sincerely,

Signature: Romain DENIS
Romain DENIS (Dec 2, 2019)

Email: romain.denis@intusurg.com
Title: VP, Regualtory Afairs and Quality Assurance
Company: Intuitive Surgical

Signature:
Kara Andersen Reiter (Nov 26, 2019)

Email: kara.reiter@intusurg.com
Title: SVP, General Counsel, Chief Compliance Officer
Company: Intuitive Surgical

cc:
Gabrielle Javier, Robotics Coordinator
Michael Geremia, Surgical Services Director
Dr. James Yu, Robotics Medical Director